Exhibit A

Recovery® Filter System for use in the Vena Cava



Information for Use

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

A. General Information

The Recovery Filter represents a new generation of venous interruption devices designed to prevent pulmonary embolism. The unique design and material of the Recovery Filter provide filtering efficiency and allow percutaneous placement through a standard 7 French I.D. angiographic introducer catheter with minimum entry site difficulties. The placement procedure is quick and simple to

The Femoral set is designed to advance through its 48 cm, 7 French I.D. introducer catheter using a flexible, nitinol pusher wire. A pad at the end of the wire is designed to push on the filter apex and a grooved segment is designed to hold and properly orient the filter legs. These components secure the filter to the pusher wire as it advances the filter, tip first, to the distal end of the catheter, positioned 1 cm below the lowest renal vein. When the tip of the filter approaches the tip of the introducer catheter, it will be positioned between the radiopaque markers on the introducer catheter. The introducer catheter and delivery assembly are then pulled back onto the pusher wire handle to unsheath and release the filter and allow it to recover to its predetermined shape. The centering system allows the Recovery Filter to be deployed with the filter tip centered and minimizes the potential for legs crossing while allowing for device removal when clinically indicated.

The Recovery Filter is designed to act as a permanent filter. When clinically indicated, the Recovery Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The Recovery Filter's elastic hooks allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed. (See Optional Removal Procedure for specific removal instructions).

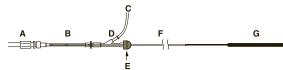
MRI Compatible: The Recovery Filter implant is MRI-safe and neither interferes with nor is affected by the operations of a MRI device.

B. Device Description

The Recovery Filter System consists of the filter and delivery system. The Recovery Filter consists of twelve, shape-memory nitinol wires emanating from a central nitinol sleeve. These twelve wires form two levels of filtration of emboli: the legs provide the lower level of filtration and the arms provide the upper level of filtration. The **Recovery** Filter is intended to be used in the inferior vena cava (IVC) with a diameter less than or equal to 28 mm.

The Recovery Filter Delivery System is illustrated in Figure A. The delivery system consists of a 7 French I.D. introducer catheter and dilator, the Recovery Filter, a storage tube with saline infusion port, and a pusher system. The Recovery Filter is packaged pre-loaded within the delivery storage tube

Figure A. Recovery Filter System



- INTRODUCER CATHETER
 FILTER STORAGE TUBE
 SALINE DRIP INFUSION SET
- ADJUSTABLE TOUHY-BORST ADAPTER
- NITINOL PUSHER WIRE
- PUSHER WIRE HANDLE

IMPORTANT: Read instructions carefully before using the Recovery Filter

C. Indications for Use

The Recovery Filter System is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated
- Recovery Filter may be removed according to the instructions supplied below under Section labeled: Optional Procedure for Filter Removal.

D. Contraindications for Use

CAUTION: If the IVC diameter exceeds 28 mm, the filter must not be inserted into the IVC.

The Recovery Filter should not be implanted in:

- Pregnant patients when fluoroscopy may endanger the fetus. Risks and benefits should be assessed carefully.
- Patients with an IVC diameter larger than 28 mm.
- Patients with risk of septic embolism.

E. Warnings

Recovery Filter Implantation

- The Recovery Filter is pre-loaded into the storage tube and is intended for single use only. Do not deploy the filter prior to proper positioning in the IVC, as the Recovery Filter cannot be safely reloaded into the storage tube.
- Do not deploy the filter unless IVC has been properly measured. (Refer to Precaution # 4.)
- Delivery of the **Recovery** Filter through the introducer catheter is advance only. Retraction of the pusher wire during delivery could result in dislodgment of the filter, crossing of filter legs or arms, and could prevent the filter from further advancement within the introducer catheter

- The Recovery Filter System is designed for femoral approaches only. Never use the Recovery Filter and Delivery System for superior approaches (jugular, subclavian or antecubital vein), as this will result in improper Recovery Filter orientation within the IVC.
- If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it as migration of the clot and/or filter may occur. Attempt filter delivery through an alternate site. A small thrombus may be bypassed by the quidewire and introducer catheter.
- Only use the *Recovery Cone®* Removal System to remove the *Recovery* Filter. Never re-deploy a removed filter.
- Never advance the guidewire or introducer catheter/dilator or deploy the filter without fluoroscopic guidance.
- 8. Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.
- Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot

See Potential Complications section for further information regarding other known filter complications

Recovery Filter Removal

- Do not attempt to remove the **Recovery** Filter if significant amounts of thrombus are trapped within the filter or if the filter tip is embedded within the vena caval wall.
- Use only the Bard Recovery Cone Removal System (packaged separately) to retrieve the Recovery Filter. Use of other removal devices has resulted in recurrent pulmonary embolism.

F. Precautions

Recovery Filter Implantation

- The filter should be placed in the suprarenal position in pregnant women and in women of childbearing age.
- 2. Anatomical variances may complicate filter insertion and deployment. Careful attention to these Instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
- Position the filter tip 1 cm below the lowest renal vein. Venacavography must always be performed to confirm proper implant site. Radiographs without contrast, which do not clearly show the wall of the IVC, may be misleading.
- When measuring caval dimensions, consider an angiographic catheter or IntraVascular Ultrasound (IVUS) if there is any question about caval morphology.
- If misplacement or sub-optimal placement of the filter occurs, consider immediate retrieval. Retrieve the Recovery Filter using the **Recovery Cone** Removal System only. Refer to the Optional Procedure for Filter Removal section for details.
- Spinal deformations: It is important to exercise care when contemplating implantation in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may make percutaneous removal of the filter more difficult.
- In patients with continued risk of chronic, recurrent pulmonary embolism, patients should be returned to anti-thrombotic therapy as soon as it is deemed safe.
- If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and use the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introduce
- The introducer catheter has radiopaque markers to assist in visualization and predeployment filter positioning. The radiopaque markers on the introducer catheter provide a "target" location between which the filter should be positioned just prior to unsheathing and deployment.
- The introducer catheter hub has a special internal design. Care should be taken to make connections firmly, but without excessive force that may cause breakage of the hub.
- It is very important to maintain introducer catheter patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become covered by clot. This will interfere with filter deployment
- Do not deliver the filter by pushing it beyond the end of the introducer catheter. To achieve proper placement, unsheath the stationary filter by withdrawing the introducer catheter.

Recovery Filter Removal

- Anatomical variances may complicate insertion and deployment of the *Recovery Cone* Removal System. Careful attention to these Instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
- Spinal deformations: It is important to exercise care when contemplating removing the Recovery Filter with the Recovery Cone Removal System in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the gen eral course of such anatomic deformations. This may require advanced interventional techniques to remove the filter.

G. Potential Complications

Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure.

Possible complications include, but are not limited to, the following:

- Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have also been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.
- Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.
- Perforation or other acute or chronic damage of the IVC wall.
- Acute or recurrent pulmonary embolism. This has been reported despite filter usage. It is not known if thrombi passed through the filter, or originated from superior or collateral vessels
- Caval thrombosis/occlusion.
- Extravasation of contrast material at time of venacavogram.
- Hematoma or nerve injury at the puncture site or subsequent retrieval site
- Hemorrhage.
- Restriction of blood flow
- Occlusion of small vessels.
- Distal embolization.
- Infection.
- Intimal tear

All these above complications have been associated with serious adverse events such as medical intervention and/or death. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

H. Equipment Required

The following equipment is required for use:

One Recovery Filter and Delivery System that contains:

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- -One 48 cm, 7 French I.D. introducer catheter and dilator set
- -One storage tube with pre-loaded *Recovery* Filter and pusher delivery system
- 0.038" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- Saline
- · Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.

If the physician chooses to percutaneously remove the **Recovery** Filter, the **Recovery Cone** Removal System is available from C. R. Bard. Inc.

I. Instructions for Use

Insertion of the 7 French Introducer Catheter and Preliminary Venography

- Select a suitable femoral venous access route, on either the right or left side, depending upon the patient's size or anatomy, operator's preference or location of venous thrombosis.
- Prep, drape and anesthetize the skin puncture site in standard fashion
- 3. Select and open the filter package. Open Kit A Introducer Catheter package.
- 4. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
- 5. Insert the J-tipped guidewire and gently advance it into the distal vena cava or iliac vein.

NOTE: If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and try the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.

- Remove the venipuncture needle over the J-tipped guidewire. Advance the 7 French introducer catheter together with its tapered dilator over the guidewire and into the distal vena cava or the iliac vein.
- NOTE: The introducer catheter has radiopaque markers to assist in visualization and predeployment filter positioning.

 The radiopaque markers on the introducer catheter provide a "target" location between which the filter should be positioned just prior to unsheathing and deployment.
- Remove the guidewire and dilator, leaving the introducer catheter with its tip in the distal vena cava or iliac vein. Flush intermittently by hand or attach to the introducer catheter a constant saline drip infusion to maintain introducer catheter patency.

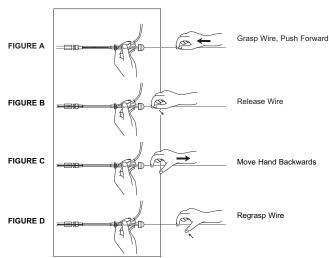
NOTE: The introducer catheter hub has a special internal design. Care should be taken to make connections firmly, but without excessive force that may cause breakage in the hub.

- Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for caval thrombi, position of renal veins and congenital anomalies. Select the optimum level for filter placement and measure the IVC diameter, correcting for magnification (typically 20 percent).
- Advance the introducer catheter to the selected level under fluoroscopic control. The guidewire and dilator should be reinserted to facilitate this. For femoral insertion, the introducer catheter tip should be 1 cm below the lowest renal vein.
- Remove the filter and delivery system from Kit B.
- 11. Connect a 500-mL bag of saline to the sideport of the Y-adapter using a standard drip infusion set. Allow the saline infusion to flow around the filter in the storage tube for 5 seconds to soften it for passage through the introducer catheter. Adjust the infusion set to provide a rapid drip rate. Tighten the Touhy-Borst adapter valve to minimize reflux of saline, but not so tight as to prevent the pusher wire from advancing freely.

NOTE: It is very important to maintain introducer catheter patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become clotted over. This will interfere with filter deployment.

12. Attach the free end of the filter storage tube directly to the introducer catheter already in the vein, allowing the saline infusion to flow into the IVC for a few seconds. The introducer catheter and filter delivery system should be held in a straight line to minimize friction.

Advancement of Filter, Illustrated



- 13. Advance the filter by moving the nitinol pusher wire forward through the introducer catheter, advancing the filter with each forward motion of the pusher wire (Figures A-D). Do not pull back on the pusher wire, only advance the pusher wire forward. For the operator's convenience, the nitinol pusher wire may be looped, without causing kinking to the nitinol material, to facilitate pusher wire handling and advancement.
- 14. Continue forward movement of the pusher wire until the filter tip advances to the radiopaque marker on the distal end of the introducer catheter. At this point, the pusher wire handle should be adjacent to the Y-adapter.

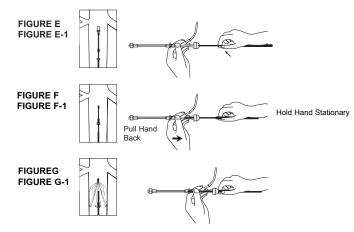
Filter Release/Deployment

Deliver and release filter as described below

Figure E: Firmly hold the pusher wire handle

Figure E-1: Filter positioned in introducer catheter between the radiopaque markers prior to deployment in IVC.

Filter Release, Illustrated



NOTE: Do not deliver the filter by pushing it beyond the end of the introducer catheter. Instead, unsheath the stationary filter by withdrawing the introducer catheter as described below.

Position the filter tip 1 cm below the lowest renal vein

Figure F: With one hand held stationary, the other hand draws the Y-adapter and storage tube assembly back completely over the handle, uncovering and releasing the filter.

Figure F-1: Unsheathing of filter in IVC.

Figure G: The position of the hands at the completion of the unsheathing process

Figure G-1: The filter deployed in the IVC.

- 16. Now withdraw the pusher wire back into the storage tube by firmly holding the Y-adapter, storage tube, and introducer catheter assembly and pulling back on the pusher wire.
- 17. Resume the intermittent saline flush or constant drip infusion to maintain introducer catheter patency.

Follow-up Venacavogram

CAUTION: Remove the Recovery Filter using the Recovery Cone only.

- A follow-up venacavogram must be performed after withdrawing the introducer catheter into the iliac vein (typically 30 mL of contrast medium at 15 mL/s).
- Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

OPTIONAL PROCEDURE FOR FILTER REMOVAL:

Removal of Recovery Filter

Equipment Required

The following equipment is required for use:

- One Recovery Cone Removal System that contains:
 - -One 75 cm, 10 French I.D. introducer catheter and dilator set
 - -One Y-adapter with Recovery Cone and pusher delivery system
- 0.035" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- Saline
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.

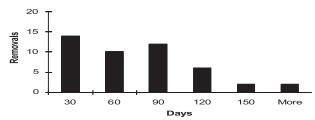
Clinical Experience

The Recovery Filter has been used in Canada by a single investigator and two colleagues at six Toronto-area hospitals in 58 subjects, under the Special Access regulations.

Although only one physician used the device, removal was performed by three physicians with different support staff and imaging equipment.

Of the 58 filters implanted, a total of 46 have been retrieved, 8 remain in place, and 4 patients have died with filters in place from causes unrelated to filter placement or retrieval (leukemia, cancer, polyarteritis and pulmonary aspergillosis, and hemorrhagic stroke). Time to removal ranged from 1 to 161 days, with an average of 60 days (see histogram below).

Time to Removal



Follow-up post retrieval has been an average of 325 days (range 1-901 days). Most (n=43) were retrieved via the right internal jugular vein, but some have been via the left internal jugular vein (n=1) and a collateral vein (n=1). One filter was removed surgically during a cancer operation where the mass was implinging on the filter. The two methods described in the Instructions for Use section were used to retrieve the filter in all but 4 cases, when a larger sheath was used, or a snare loop was attempted instead of using the *Recovery Cone* removal system. There was one case of asymptomatic pulmonary embolism when using the larger sheath.

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The only other removal complication was a fractured filter arm and hook. This filter was placed infrarenally in a pregnant woman during the third trimester at the level of L1-L2. The fracture was believed to be secondary to stresses due to delivery and placement infrarenally, causing severe deflection and embedding of the hook into the bony tissue of the vertebrae. The filter was retrieved, with the hook missing.

Clinical Experience Summary Table			
Recovery Filters Implanted	58		
Percutaneous Filter Removals	45		
Surgical Filter Removals	1 (Concurrent to tumor resection)		
Patient Age	8-89 years (52 years average)		
Reason for Filter Placement			
Contraindication to anticoagulation	40		
Complications associated with anticoagulation	13		
Failure of anticoagulation	3		
Prophylaxis	2		
Time to removal	1-161 days (60 days average)		
Follow-up post-removal	1-901 days (325 average)		

Filter Removal Complications		
Technical	0	
Hook fracture secondary to stresses due to labor and birth and infrarenal placement	1	
Asymptomatic pulmonary embolism post-removal	1	

Procedural Instructions

Insertion of the Introducer Catheter

- Select a suitable jugular venous access route on either the right or left side depending upon the patient's size or anatomy, operator's preference, or location of venous thrombosis.
- 2. Prep, drape and anesthetize the skin puncture site in standard fashion.
- 3. Select and open the Recovery Cone Removal System package. Open Kit A Introducer Catheter package.
- 4. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
- 5. Insert the guidewire and gently advance it to the location of the Recovery Filter for removal.
- 6. Remove the venipuncture needle over the auidewire.
- Pre-dilate the accessed vessel with a 12 French dilator.
- 8. Advance the 10 French introducer catheter together with its tapered dilator over the guidewire and into the vein.

NOTE: The introducer catheter has a radiopaque marker at the distal end of the catheter sheath to assist in visualization.

- Remove the guidewire and dilator, leaving the introducer catheter with its tip in the appropriate location. Flush intermittently
 by hand or attach to the catheter a constant saline drip infusion to maintain introducer catheter patency.
- Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for thrombus within the filter. If there is significant thrombus within the filter, do not remove the Recovery Filter.

Recovery Cone Insertion and Delivery

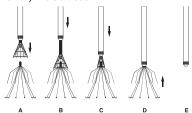
- 11. Remove the Recovery Cone and pusher system from Kit B.
- 12. Flush the central lumen of the cone catheter and wet the cone with saline—preferably heparinized saline.
- 13. Slowly withdraw the cone into the Y-adapter to collapse the cone.

NOTE: The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly delivered through the catheter.

- 14. Connect a 500 mL bag or a syringe of saline to the sideport of the Y-adapter. Allow the saline infusion to flow around the Recovery Cone in the Y-adapter for 5 seconds. Tighten the Touhy-Borst adapter valve to minimize reflux of saline toward the feeder, but not so tight as to prevent the pusher shaft from advancing freely.
- 15. Attach the male end of the Y-adapter with the collapsed cone directly to the introducer catheter. The introducer catheter and filter delivery system should be held in a straight line to minimize friction.
- Advance the cone by moving the pusher shaft forward through the introducer catheter, advancing the cone with each forward motion of the pusher shaft.
- 17. Continue forward movement of the pusher shaft until the cone advances to the radiopaque marker on the distal end of the introducer catheter. Unsheath to open the cone by stabilizing the pusher shaft and retracting the introducer catheter.

Capture of Recovery Filter

Filter Removal, Illustrated



18. The capture of the *Recovery* Filter is illustrated in Figures A-E:

Figure A: After the cone has been opened superior to the filter, advance the cone over the filter tip by holding the introducer catheter stationary and advancing the pusher shaft. It is recommended to obtain an anterior-oblique fluoroscopic image to confirm that the cone is over the filter tip.

Figure B: Close the cone over the filter tip by advancing the introducer catheter over the cone while holding the pusher shaft stationary.

Figure C: Continue advancing the introducer catheter over the cone until the cone is within the introducer catheter.

Figure D: With the cone collapsed over the filter, remove the filter by stabilizing the introducer catheter and retracting the pusher shaft in one, smooth, continuous motion.

Figure E: The filter has been retracted into the catheter.

Examine the filter to assure that the complete filter has been removed.

Follow-up Venacavogram

- A follow-up venacavogram may be performed prior to withdrawing the introducer catheter (typically 30 mL of contrast medium at 15 mL/s).
- Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

Guidewire - Assisted Technique

Due to anatomical variances with respect to the position of the **Recovery** Filter, guidewire-assisted techniques may be used. **Use of a Guidewire**

If it is difficult to align the cone with the **Recovery** Filter tip, one may use a guidewire to facilitate advancement of cone over the filter tip.

Withdraw the introducer catheter and cone shaft away from the filter tip. Insert a 0.035" guidewire through the central lumen (Jtipped or angled tip; a hydrophilic-coated guidewire is recommended). Advance the guidewire through the cone and through the filter near the filter tip.

After it has been confirmed that the guidewire is in contact with or in close proximity to the filter tip, advance the cone over the quidewire to the filter tip.

Advance the introducer catheter to slightly collapse the cone over the Filter tip. Withdraw the guidewire into the pusher shaft. Continue removing the Filter as described in step 18.

J. How Supplied

Each Recovery Filter is supplied preloaded in a storage tube. Each Recovery Filter is sterile and nonpyrogenic unless the package is damaged or opened, and is ready for single use only. The storage tube and delivery system are pre-assembled. If the filter is inadvertently discharged, do not attempt to re-sterilize or reload it.

Note: After use, the Recovery Filter Delivery System and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations. The Recovery Filter should be stored in a cool (room temperature), dry place.

K. Warranty

Bard Peripheral Vascular warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in Bard Peripheral Vascular's sole discretion or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty. TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTIABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

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Labeling Issue Date: 12/04

In the event 3 years have elapsed between this date and product use, the user should contact C. R. Bard, Inc. to see if additional product information is available.

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U.S. Patent No. 6,007,558 and 6,258,026. Other Patents Pending.

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